510(k) Summary of
Safety & Effectiveness

Submitter:

- SPSmedical Supply Corp.
  6789 West Henrietta Road
  Rush, NY 14543 U.S.A.
  Phone: (585)-359-0130 Fax: (585)-359-0167

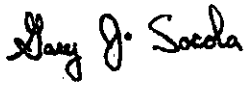
- Establishment FDA Registration No.: 1319130

- 510K No. K122024

NOV 26 2013

- Date Summary was Prepared Novemeber20th, 2013

- Gary J. Socola
  Printed name of person submitting for 510(k)

- 
  Signature of person submitting for 510(k)

- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SporView® 10 Steam Self Contained Biological Indicator
Classification Name:	Sterilization Process Biological Indicator
Common Name:	Self-Contained Biological Indicator
Device Classification:	Class II, Regulation Number 880.2800
Product Code:	FRC
Predicate Device:	SporView® Steam Self Contained BI (K070595 and K111515)

Device Description:

The SporView® 10 Self Contained Steam BI (SCBI) consists of a self-contained unit that includes bacterial spores of *Geobacillus stearothermophilus* ATCC #7953 inoculated onto a paper filter carrier and a small glass ampoule containing a nutrient broth culture medium containing bromocresol purple as a pH indicator encased in a plastic vial that serves as the culture tube. Biochemical activity of the G. *stearothermophilus* organism produces acid by-products that cause the media to change color from purple to yellow. A visual pH color change and/or turbidity indicates' a steam sterilization process failure.

SporView® 10 SCBI's are conventional spore growth readout biological indicators specifically designed for rapid and reliable monitoring of steam sterilization processes without the use of enzyme based technology or specific and specialized incubators or monitoring devices.

SporView® 10 Steam Self Contained Biological Indicators comply with the performance requirements of ANSI/AAMI/ISO 11138-1 and ANSI/AAMI/ISO 11138-3:2010, the USP requirements for SCBI's and the FDA's Biological Indicator guidance document on Premarket Notification 510(k) Submissions.

SPSmedical Supply Corp. is using its SporView® Self Contained Steam BI (K070595 and K111515) to show equivalence to the proposed SporView® 10 Self Contained Steam BI device modification. Both devices are essentially the same device with only one difference; that is the proposed device has a modified media formulation that was validated for a lower reduced incubation time than the predicate device.

Intended Use:

SporView® 10 Steam is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of saturated steam sterilization processes. SporView® 10 self-contained biological indicators have a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles:

Sterilization Mode	Temperature	Time
Gravity	121°C	30 minutes
Gravity	132°C	15 minutes
Gravity	134°C	4 minutes
Gravity - Flash	132°C	3 minutes
Gravity - Flash	132°C	10 minutes
Dynamic Air	121°C	20 minutes
Dynamic Air	121°C	30 minutes
Dynamic Air	132°C	3 minutes
Dynamic Air	132°C	4 minutes
Dynamic Air	134°C	4 minutes
Dynamic Air	135°C	3 minutes

Statement of Similarity to the Legally Marketed Predicate Device:

- Both devices are essentially the same device tested at different incubation times.
- Both are intended to monitor steam sterilization cycles.
- Both utilize the same strain of bacterial spores.
- Both utilize the same carrier material.
- Both are activated in the same manner.
- Both are incubated at the same temperature.
- Both use USP compliant culture mediums.
- Both had media growth promotion studies validated for growth of the G. *stearothermophilus* organism after exposure to a steam cycle of 132°C for 10 minutes exposure time.

Non-Clinical Testing:

Testing was performed in order to validate the indicators label claims and performance characteristics according to the reduced incubation time protocol described in the FDA guidance document entitled "Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions". Multiple lots of indicators and media were tested and all lots met the FDA's defined acceptance criteria of >97% for a reduced incubation time of 10 hours.

Testing was also performed to validate the indicators other label claims and performance characteristics. Multiple lots of indicators were tested for;

- Resistance
- Spore population
- Effects of holding time
- Stability of the color change
- Media Evaporation
- Survival Response Time
- Effects of carrier and package materials
- Media recovery after exposure to a steam cycle of 132°C for 10 minutes

All test results met the defined acceptance criteria.

Conclusion:

Supportive data has demonstrated that the SPSmedical SporView® 10 Steam Self Contained Biological Indicator is equivalent to the legally marketed predicate devices but with a lower reduced incubation time. The proposed device is as safe and effective as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

SPS Medical Supply Corporation
Mr. Gary J. Socola
Vice President, Scientific Affairs
6789 West Henrietta Road
RUSH, NEW YORK 14543

Re: K122024
Trade/Device Name: SporView® 10 Steam Self Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: November 12, 2013
Received: November 14, 2013

Dear Mr. Socola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

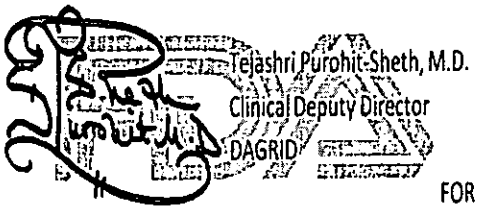
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin Keith
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K122024

Device Name: SporView® 10 Steam Self Contained BI

Indications For Use:

SporView® 10 Steam is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of saturated steam sterilization processes. SporView® 10 self-contained biological indicators have a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles:

Sterilization Mode	Temperature	Time
Gravity	121°C	30 minutes
Gravity	132°C	15 minutes
Gravity	134°C	4 minutes
Gravity - Flash	132°C	3 minutes
Gravity - Flash	132°C	10 minutes
Dynamic Air	121°C	20 minutes
Dynamic Air	121°C	30 minutes
Dynamic Air	132°C	3 minutes
Dynamic Air	132°C	4 minutes
Dynamic Air	134°C	4 minutes
Dynamic Air	135°C	3 minutes

Prescription Use _____ AND/OR Over-The-Counter Use __X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth F. Claverie -S
2013.11.24 23:30:46 -05'00'